Sub C3 > g. resecting the selected portion of tissue from the surrounding portion of tissue.

50. (Amended) The method according to claim 49, further comprising the steps of:

Sub Q1

h. moving, after the selected portion of tissue has been resected, at least one of the anvil and the stapling mechanism relative to the other from the stapling position to release the surrounding portion of tissue therefrom; and

i. moving at least one of the anvil and the stapling mechanism relative to the other to the closed position to retain the selected portion of tissue therein.

B5 Cont.

51. (Amended) The method according to claim 49, wherein, when the selected portion of tissue is drawn into the tissue receiving chamber in step (d), the selected portion of tissue is folded over so that two full thickness portions of the tissue are received between the anvil an the stapling mechanism.

REMARKS

Claims 36-51 remain pending in this application. Each of these claims has been amended to more particularly point out and distinctly claim the subject matter of the invention. In view of the above amendments and the following remarks, it is respectfully submitted that all of the presently pending claims are allowable.

Claims 38, 41 and 43-51 stand rejected under 35 U.S.C. § 112, second paragraph, as indefinite for failing to particularly point out and distinctly claim the invention. In view of the above amendments, it is respectfully submitted that all of the presently pending claims fully comply with § 112 and it is respectfully requested that this rejection be withdrawn.

Claims 36-38, 40-43 and 49 stand rejected under 35 U.S.C. § 103 as obvious over Tsuruta (U.S. Patent No. 5,389,098) in view of Sauer (U.S. Patent No. 5,562,694). The Examiner stated in support of the rejection that Tsuruta shows a stapling assembly substantially as claimed except for the grasper for drawing tissue into the cutting zone. The Examiner further stated that Sauer

shows a grasper as claimed and that it would have been obvious to have combined the stapling assembly of Tsuruta with the grasper of Sauer to achieve the claimed invention.

Claim 36 recites an apparatus for resecting tissue within a body lumen, comprising "*an operating capsule selectively coupleable to a flexible endoscope*, the operating capsule, when in an operative position, being located within a body lumen adjacent to a selected portion of tissue to be resected, the operating capsule including a suturing assembly and defining a cutting zone adjacent to the suturing assembly" in combination with "a tissue grabber drawing the selected portion of tissue into the cutting zone, wherein the suturing assembly fastens together portions of tissue adjacent to the selected portion of tissue."

In contrast, Tsuruta shows various rigid surgical instruments which are inserted into body cavities *via incisions made in body walls*. (Col. 2, lines 44-46). None of these devices includes an operating capsule which is coupleable to a flexible endoscope. As flexible endoscopes are used for insertion into body cavities through natural orifices and not through surgical incisions, there is no reason to couple such a device to an endoscope. The rigidity of these devices also makes them unsuitable for use with flexible endoscopes. Furthermore, none of these devices includes an operating capsule which, when in an operative position, is located within a body lumen. Rather, the devices of Tsuruta include a stapling mechanism at the distal end of a rigid shaft which, when in an operative position, extends from outside the body, through an incision into a body cavity. None of the Tsuruta devices includes a capsule which is located entirely within a body cavity, as recited in claim 36.

Sauer also shows a rigid instrument which is not coupleable to a flexible endoscope and which includes no capsule which is located entirely within a body cavity. Although Sauer describes the device as useful in endoscopic surgical procedures, it is clear that the device is not intended for use with a flexible endoscope. Specifically, Sauer states that endoscopic procedures involve "incising through body walls for examining, viewing and/or operating on various bodily organs or structures" with a trocar being employed to create the incision and tubes being inserted through the incision and left in place in the abdominal wall so that tools may be inserted

therethrough. (Col. 1, lines 17-24). Thus, the elongated body portion 14 is rigid and is not selectively coupleable to a flexible endoscope. Nor would such a coupling be of any use with this device.

For these reasons, it is respectfully submitted that neither Tsuruta nor Sauer either show or suggest "*an operating capsule selectively coupleable to a flexible endoscope*, the operating capsule, when in an operative position, being located within a body lumen adjacent to a selected portion of tissue to be resected," as recited in claim 36. Furthermore, both of these references are specifically directed to rigid devices for use with open surgery and therefore teach away from the a device for use with a flexible endoscope.

Finally, claim 49 recites a method for resecting tissue from within a body lumen, comprising the steps of "inserting *an operating head coupled to a flexible endoscope* into a body lumen" in combination with the step of "*advancing the operating head over the endoscope* within the body lumen to a desired position relative to a selected portion of tissue to be resected."

For the reasons stated above in regard to claim 36, it is respectfully submitted that neither Tsuruta nor Sauer either shows or suggests a method including these steps and this rejection should be withdrawn.

It is therefore respectfully submitted that claims 36 and 49 are not rendered obvious by Tsuruta and Sauer, either taken alone or in combination and this rejection should be withdrawn. Because claims 37, 38 and 40 - 43 depend from claim 36, it is respectfully submitted that these claims are also allowable.

Claim 39 stands rejected under 35 U.S.C. § 103 as obvious over Tsuruta and Sauer as applied to claim 36 in further view of Bessler (U.S. Patent No. 5,197,649). The Examiner stated, in support of the rejection, that Tsuruta in view of Sauer shows the invention substantially as claimed except for the flexible endoscope and that Bessler shows such an endoscope.

Initially it is noted that, as discussed above in regard to claim 36, the rigid devices of Sauer and Tsuruta are for very different applications (i.e., open surgery) than the claimed device and that these differences taught away from combinations with flexible endoscopes. Clearly none of the references provides the motivation for such a combination. Specifically, the device of Bessler is intended to eliminate the type of open procedures for which the devices of Tsuruta and Sauer are designed and adding a flexible endoscope as shown to either of these devices (or a hybrid thereof) would bring back the problems that the Bessler device is attempting to address. Specifically, there is clearly no motivation in either Tsuruta or Sauer to combine with a flexible endoscope as the flexibility and steering capabilities of such an endoscope would be useless within the rigid bodies of these devices. And the device of Bessler is an attempt to eliminate the need for incisions in performing operations such as anastamoses of the colon. Thus, combining the teaching of Bessler with any rigid device is completely contradictory to the teachings of that reference. Among the disadvantages of prior devices discussed, Bessler states that "[m]any of the available devices have a rigid structure which preclude (sic) their application for other than straight intestines." Thus, the combination of this device with a rigid structure is clearly taught away from by Bessler.

It is therefore respectfully submitted that none of the cited references provides any motivation for the combination suggested by the Examiner and that, therefore, this rejection is based on an impermissible hindsight reconstruction of the invention. For this reason and for the reasons stated above in regard to claim 36, it is respectfully submitted that claim 39 is not rendered obvious by Tsuruta, Sauer and Bessler and that this rejection should be withdrawn.

Claims 44-48 stand rejected under 35 U.S.C. § 103 as obvious over Tsuruta in view of Bessler. The Examiner stated, in support of the rejection that Tsuruta discloses the invention substantially as claimed except for the internal endoscope, but that Bessler shows such an endoscope. Claims 39 and 44-50 stand rejected under 35 U.S.C. § 103 as obvious over Sauer in view of Bessler. The Examiner stated, in support of the rejection that Sauer discloses the invention substantially as claimed except for the internal endoscope, but that Bessler shows such an endoscope.

Claim 44 recites a system for resecting tissue from within a body lumen, comprising "*a flexible endoscope*" and "*an operating head selectively coupleable to the endoscope*, the operating head including an anvil and a stapling mechanism moveable with respect to one another between a closed position in which the anvil and the stapling mechanism are adjacent to one another and a tissue receiving position in which the anvil is separated from the stapling mechanism" in combination with "*a flexible sheath extending from a proximal end of the operating head so that, when the operating head is in an operative position within a body lumen, a proximal end of the flexible sheath extends out of the body lumen*" and "a control handle coupled to the proximal end of the flexible sheath."

For the reasons stated above in regard to claim 36, it is respectfully submitted that neither Tsuruta nor Sauer either shows or suggests a system including "*a flexible endoscope*" and "*an operating head selectively coupleable to the endoscope*," and clearly neither shows nor suggests "*a flexible sheath extending from a proximal end of the operating head so that, when the operating head is in an operative position within a body lumen, a proximal end of the flexible sheath extends out of the body lumen*," as recited in claim 44.

As stated above in regard to claim 39, the rigid devices of Sauer and Tsuruta are for very different applications (i.e., open surgery) than the claimed device and these differences teach away from combinations with flexible endoscopes. Thus, none of the references provides the motivation for such a combination. Furthermore, as discussed above, combining the teaching of Bessler with any rigid device is completely contradictory to the teachings of that reference is clearly taught away from by Bessler.

Thus, it is respectfully submitted that none of the cited references either shows or suggests a system including "*a flexible endoscope*" and "*an operating head selectively coupleable to the endoscope*," and clearly neither shows nor suggests "*a flexible sheath extending from a proximal end of the operating head so that, when the operating head is in an operative position within a body lumen, a proximal end of the flexible sheath extends out of the body lumen*," as recited in claim 44.

It is therefore respectfully submitted that none of the cited references provides any motivation for the combination suggested by the Examiner and that, therefore, this rejection is based on an impermissible hindsight reconstruction of the invention. For this reason and for the reasons stated above in regard to claim 36, it is respectfully submitted that claims 39 and 44-50 are not rendered obvious by Tsuruta, Sauer and Bessler and that this rejection should be withdrawn.

Therefore, it is respectfully submitted that claim 44 is not rendered obvious by Tsuruta, Sauer and Bessler and this rejection should be withdrawn. Because claims 45-48 depend from and include all of the limitations of claim 44, it is submitted that these claims are also allowable.

Claims 36-51 stand rejected under the judicially created doctrine of obviousness-type double patenting over the claims of U.S. Patent Nos. 5,868,760 and 6,264,086. In view of the Terminal Disclaimer submitted herewith, it is respectfully submitted that this rejection has been obviated and should be withdrawn.

It is respectfully submitted that all of the presently pending claims are allowable and that the present application is in condition for allowance. Therefore, a prompt and favorable action on the merits is earnestly solicited. The Examiner is invited to contact the undersigned at (212) 898-8873 to discuss any matter concerning this application.

Respectfully submitted,

Dated: December 21, 2001

By: _____
Patrick J. Fay
~~Reg. No. 35,508~~

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ATTACHMENT A

36. (Amended) An apparatus for resecting tissue within a body lumen, comprising:

an operating capsule selectively coupleable to a flexible endoscope, the operating capsule, when in an operative position, being entirely located within a body lumen adjacent to a selected portion of tissue to be resected, the operating capsule including a suturing assembly and defining a cutting zone adjacent to the suturing assembly; and

a tissue grabber drawing the selected portion of tissue into the cutting zone, wherein the suturing assembly fastens together portions of tissue adjacent to the selected portion of tissue.

38. (Amended) The apparatus of claim 36, wherein the suturing assembly includes an [the] anvil and a stapling mechanism [are] movably coupled to one another for movement between a closed position and a tissue receiving position.

41. (Amended) The apparatus of claim 36, further comprising a control handle which, when the operating capsule is in an operative position within a body lumen, remains outside the body, and a first flexible control element extending from the control handle through the sheath to the operating head.

43. (Amended) The apparatus of claim 38, wherein the anvil and the [suturing] stapling mechanism are rotatably coupled to one another for movement between the closed and tissue receiving positions.

44. (Amended) A system for resecting tissue from within a body lumen, comprising:

a[n] flexible endoscope;

an operating head selectively coupleable to the endoscope, the operating head including an anvil and a stapling mechanism moveable with respect to one another between a closed position in which the anvil and the stapling mechanism are adjacent to one another and a tissue receiving position in which the anvil is separated from the stapling mechanism;

a flexible sheath extending from a [distal] proximal end of the operating head so that, when the operating head is in an operative position within a body lumen, a proximal end of the flexible sheath extends out of the body lumen; and

a control handle coupled to the proximal end of the flexible sheath.

47. (Amended) The system of claim 45, wherein the operating head further comprises a position adjusting mechanism for adjusting the position of the anvil relative to the stapling mechanism, the system further comprising a [second] position adjusting flexible control member extending between the control handle and the position adjusting mechanism.

48. (Amended) The system of claim [44] 47, wherein the position adjusting mechanism

moves the anvil and the stapling mechanism relative to one another between the tissue receiving position and a stapling position in which the anvil and the stapling mechanism are separated by a predetermined gap, wherein the predetermined gap is smaller than a separation between the anvil and the stapling mechanism when in the tissue receiving position.

49. (Amended) A method for resecting tissue from within a body lumen, comprising the steps of:

a. inserting an operating head coupled to a flexible endoscope into a body lumen, wherein the operating head includes an anvil and a stapling mechanism;

b. advancing the operating head over the endoscope within the body lumen to a desired position relative to a selected portion of tissue to be resected;

c. moving at least one of the anvil and the stapling mechanism relative to the other from a closed position in which the anvil and the stapling mechanism are adjacent to one another to a tissue receiving position in which the anvil is separated from the stapling mechanism;

[c]d. drawing the selected portion of tissue into a tissue receiving chamber within the operating head;

[d]e. moving at least one of the anvil and the stapling mechanism relative to the other from the tissue receiving position to a stapling position in which a surrounding portion of tissue adjacent to the selected portion of tissue is clamped between the anvil and the stapling mechanism;

[e]f. stapling the surrounding portion of tissue; and

[f]g. resecting the selected portion of tissue from the surrounding portion of tissue.

50. (Amended) The method according to claim 49, further comprising the steps of:

[g]h. moving, after the selected portion of tissue has been resected, at least one of the anvil and the stapling mechanism relative to the other from the stapling position to release the surrounding portion of tissue therefrom; and

[h]i. moving at least one of the anvil and the stapling mechanism relative to the other to the closed position to retain the selected portion of tissue therein.

51. (Amended) The method according to claim 49, wherein, when the selected portion of tissue is drawn into the tissue receiving chamber in step ([c]d), the selected portion of tissue is folded over so that two full thickness portions of the tissue are received between the anvil an the stapling mechanism.